# Racivir



## **HIV/AIDS-Related Uses**

Racivir (RCV) is a nucleoside reverse transcriptase inhibitor with potent and selective activity against both HIV and hepatitis B virus (HBV) in cell culture and in animal models. It has been well tolerated in preclinical safety assessment studies in animals and is now being studied in humans for the treatment of HIV.[1]

### Non-HIV/AIDS-Related Uses

Racivir is active in vitro against HBV.[2]

## **Pharmacology**

In a Phase I/II dosing study, RCV was administered to HIV infected treatment-naive volunteers in combination with stavudine and efavirenz for 14 days. RCV was administered once daily at doses of 200, 400, or 600 mg. The combination regimens resulted in a rapid initial drop in viral load, with mean reductions ranging from 1.13 to 1.42 logs by Day 4. Mean HIV RNA levels continued to drop more slowly through the end of treatment on Day 14, with mean drops in viral load ranging from 2.02 to 2.43 logs. Upon cessation of therapy, HIV RNA levels remained suppressed at all dose levels for more than 2 weeks. Mean viral loads ranged from 2.1 to 2.6 logs below baseline through Day 28. By Day 35, HIV RNA levels began to increase, but still remained more than 1 log below baseline levels.

RCV in combination with stavudine and efavirenz was well tolerated at all doses tested.[3]

# **Drug and Food Interactions**

In clinical trials, racivir was administered with stavudine and efavirenz. There was no evidence that co-administration of stavudine and efavirenz had an adverse effect on the pharmacokinetics of racivir.[4]

### **Contraindications**

In a single-dose pharmacokinetic study of racivir, all adverse events were mild and occurred no more frequently than with placebo. Headache and fatigue were the most common adverse effects.[5]

# **Clinical Trials**

For information on clinical trials that involve Racivir, visit the ClinicalTrials.gov web site at http://www.clinicaltrials.gov. In the Search box, enter: Racivir AND HIV Infections.

# **Dosing Information**

Mode of Delivery: Oral.[6]

## **Other Names**

RCV[7]

[+/-]-2-hydroxymethyl-5-[5-fluorocytosine-1-yl]-1,3-oxathiolane[8]

### **Manufacturer Information**

Racivir
Pharmasset, Inc.
US Research Operations
1860 Montreal Road
Tucker, GA 30084
(678) 395-0035

### **For More Information**

Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday Friday, 12:00 p.m. (Noon) 5:00 p.m. ET
- Via Live Help: http://aidsinfo.nih.gov/live\_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET

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## References

- 1. Conf Retroviruses Opportunistic Infect. 10th; February 2003. Abstract P552.
- 2. Conf Retroviruses Opportunistic Infect. 10th; February 2003. Abstract P552.
- 3. Conf Retroviruses Opportunistic Infect. 10th; February 2003. Abstract P552.
- 4. Pharmasset, Inc Available at: http://www.pharmasset.com/go. Accessed 10/06/03.
- 5. Pharmasset, Inc Available at: http://www.pharmasset.com/go. Accessed 10/06/03.
- 6. Conf Retroviruses Opportunistic Infect. 10th; February 2003. Abstract P552.
- 7. Conf Retroviruses Opportunistic Infect. 10th; February 2003; Abstract 552
- 8. Conf Retroviruses Opportunistic Infect. 10th; February 2003; Abstract 552